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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,095	10/06/2006	Gerd Bayer	117163.00157	8142

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EXAMINER	
BAYS, PAMELA M	

ART UNIT	PAPER NUMBER
4118	

NOTIFICATION DATE	DELIVERY MODE
11/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,095	BAYER ET AL.	
	Examiner	Art Unit	
	PAMELA BAYS	4118	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *23 March 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hendriks et al (U.S. Patent No. 5,866,113).

3. Regarding Claim 1 and 17, Hendriks et al discloses a medical device such as "nerve electrodes, muscle electrodes, implantable pulse generators ...and defibrillators," of which would inherently have a metallic base body, (Col. 4, Lines 13-15) with various layers (Fig. 3) of a biocompatible substance (Col. 3, Lines 7-9) . In addition, Hendriks et al discloses that a bimolecular coating to the medical device (Col. 3, Lines 7-9) can include "hyaluronic acid" (Col. 4, Line 37), a polysaccharide, which could be in the form of individual substances, copolymers or block polymers ("polymerized biomolecules," Col 4, Lines 46-49).

4. Regarding Claim 18, Hendriks et al discloses a stimulation electrode with a polysaccharide layer coating, that additionally uses an "immobilization approach" to prohibit movement of the biomolecules that uses "covalent coupling of the majority of the biomolecules" on the surface of the implant (Col 5, Lines 31-32, Lines 38-39).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al.

7. Regarding Claims 2 and 3, Hendriks et al discloses the claimed invention as described above except for the molecular weight of the hyaluronic acid after a sterilization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer properties by selecting hyaluronic acid with the appropriate molecular weight for the purpose of tissue compatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

8. Claims 4 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Pastorello (U.S. Patent No. 6,642,213).

9. Regarding Claims 4, 5, and 7, Hendriks et al discloses a stimulation electrode with a polysaccharide layer coating, with inherent internal and external areas, as described above. However, Hendriks et al does not disclose the rate of degradation of

the layer. Pastorello teaches an implantable medical prosthesis containing a hyaluronic acid derivative (Col.2, Lines 45-48), and that "the chemical structure of the hyaluronic acid derivative used and according to the degree of esterification [has] the advantage of having tensile strength and degradation times that can be adjusted according to the requirement of the area to be reconstructed" (Col. 3, Lines 57-61). It would have been obvious to one of ordinary skill in the art at the time of the invention to select the appropriate chemical structure and degree of esterification of the hyaluronic acid to control the rate of in vivo degradation, as taught by Pastorello, in order to limit the external area to less than 100 days and prolong the internal area to greater than two years in order to promote tissue compatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

10. Regarding Claims 6 and 8, Hendriks et al and Pastorello describe a stimulation electrode with a variably degradable polysaccharide layer coating as described above. However, Hendriks and Pastorello do not disclose the thickness of the internal or external portions of the polysaccharide layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer thickness on the electrode in order to promote tissue compatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Pastorello, and further in view of Lahtinen (U.S. 2003/0059463).

12. Regarding Claim 9, Hendriks et al and Pastorello describe a stimulation electrode with a variably degradable polysaccharide layer coating as described above. However, they do not disclose multiple partial layers of a polysaccharide layer each having different degradation behaviors, the degradation behavior within each partial layer being able to be fixed continuously changeably or constant over the partial layer. Lahtinen teaches that "biocompatible-polymeric carrier matrix, such as alginate, collagen, hyaluronic acid" (Page 13, Paragraph 112, Col. 2, Bottom) can be added to a medical device, and that, "Several layers of polymers can be utilized and several different polymers can be combined on the same implant... Also, one or more surfaces of the implant can be coated with one or more additional coats of polymer that is the same or different from the second polymer" (Page 14, Paragraph 112, Col. 1, Mid-page). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add multiple hyaluronic acid layers with different degradation properties by altering the chemical structure and degree of esterification of the hyaluronic acid, as taught by Pastorello and Lahtinen, for the purpose of providing different degradation behaviors on coating of the electrode to promote tissue compatibility.

13. Regarding Claims 10 and 12, Hendriks et al, Pastorello, and Lahtinen describe a stimulation electrode with a variably degradable polysaccharide layer coating comprising of multiple partial with different degradation behavior in multiple layers as

described above. However, they do not describe weight-percent degradation of the layers during specific time intervals. It would have been obvious to one of ordinary skill in the art at the time of the invention to select the appropriate chemical structure and degree of esterification of the hyaluronic acid to control the rate of in vivo degradation by weight percent, as taught by Pastorello, of each layer in the polysaccharide coating as taught by Lahtinen, in order to promote tissue compatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

14. Regarding Claims 11, and 13-15, Hendriks et al, Pastorello, and Lahtinen describe a stimulation electrode with a variably degradable polysaccharide layer coating comprising of multiple partial with different degradation behaviors layers as described above. However, they do not disclose the thickness of the internal or external portions of the polysaccharide layer, or of the entire layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer thickness on the electrode, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Prutchi (U.S. Patent No. 6,152,882).

16. Regarding Claim 16, Hendriks et al discloses a stimulation electrode with a polysaccharide layer coating as described above. However, Hendriks et al does not

disclose the addition dexamethasone and/or dexamethasone sodium phosphate (DMNP) in a concentration sufficient to produce a pharmacological effect. Prutchi teaches a catheter (Fig 9) with an electrode 122 including a steroid drug that "may be a sodium salt of dexamethasone phosphate" (Col. 21, Lines 67-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add a steroid drug such as DMNP to an implantable electrode, as taught by Prutchi, for the purpose of improving tissue compatibility.

17. Claims 19-22 are rejected 35 U.S.C. 103(a) as being unpatentable over Hendriks et al in view of Lahtinen, and further in view of Collombel (U.S. Patent No. 5,166,187).

18. Regarding Claims 19 and 21, Hendriks et al discloses a medical device such as "nerve electrodes, muscle electrodes, implantable pulse generators, ...and defibrillators" (Col. 4, Lines 13-15) with various layers (Fig. 3)) to "promot[e] tissue integration" (Col. 1, Line 39). In addition, Hendriks et al discloses that a bimolecular coating to the medical device (Col. 3, Lines 7-9) can include "hyaluronic acid" (Col. 4, Line 37). However, Hendriks et al does not disclose the polysaccharide layer comprises an adhesion-promoting layer or partial layer made of chitosan. Lahtinen teaches that "biocompatible-polymeric carrier matrix, such as alginate, collagen, hyaluronic acid" (Page 13, Paragraph 112, Col. 2, Bottom) can be added to a medical device, and that, "Several layers of polymers can be utilized and several different polymers can be combined on the same implant... Also, one or more surfaces of the implant can be coated with one or more additional coats of polymer that is the same or different from

the second polymer" (Page 14, Paragraph 112, Col. 1, Mid-page). Moreover, Collombel teaches the usage of chitosan in a biomaterial to use as a "cross-linking agent" (Col. 8, Lines 47-48) for adhesion, and also including hyaluronic acid to promote cell adhesion and biocompatibility (Col. 8, Lines 62-65). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to add both hyaluronic acid and chitosan to a coating, as taught by Lahtinen and Collombel, in order to promote biocompatibility and cell adhesion to an electrode implant.

19. Regarding Claim 20, Hendriks et al, Lahtinen, and Collombel disclose a polysaccharide layer coating comprising of hyaluronic acid and chitosan as described above. However, they do not disclose the thickness of the chitosan polysaccharide layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the layer thickness on the electrode to best promote biocompatibility, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

20. Regarding Claim 22, Hendriks et al, Lahtinen, and Collombel disclose a polysaccharide layer coating comprising of hyaluronic acid and chitosan as described above. However, they do not disclose the specific weight-percent of the chitosan in the polysaccharide layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the weight-percent of the chitosan in the polysaccharide layer to best promote adhesion, since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-15 and 17-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 and 25 of copending Application No. 10/561,774. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-21 and 25 of copending Application No. 10/561,774 disclose all of the claimed elements including an implantable tissue stimulator comprising the coating system as recited in the copending application No. 10/561,774.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAMELA BAYS whose telephone number is (571)270-7852. The examiner can normally be reached on Monday-Friday, 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang Thanh can be reached on (571)272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. B./
Examiner, Art Unit 4118

/Quang D. Thanh/
Supervisory Patent Examiner,
Art Unit 4118